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Vertebral artery Ischaemia Stenting Trial

Submission date
15/02/2008

Recruitment status
No longer recruiting

Registration date
04/03/2008

Overall study status
Completed

Last Edited
21/08/2019

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Narrowing (stenosis) of the vertebral and basilar arteries in the neck, which supply blood to the back of the brain, is an important cause of stroke. Patients with stroke due to vertebral and basilar artery stenosis have an increased risk of further stroke. We can now treat vertebral stenosis with a stent. This involves placing a small tube made of wire mesh inside the narrowed artery in the neck. The stent is passed into the artery through a small tube (catheter) inserted into the groin under local anaesthetic. Once in position across the narrowing the stent is opened out where it acts like a spring to keep the artery open. Stenting has been successfully used in the arteries supplying the heart and the legs and it is now a routine treatment for these diseases. It has also been used in many cases of narrowing of the arteries at the front of the brain (carotid arteries). Hundreds of cases of vertebral stenosis have been treated by stents worldwide but we don't yet have any information as to whether it is better to perform stenting or to treat with drugs alone. Therefore in this study, which will be carried out in many different hospitals, we are comparing whether stenting is better than standard drug treatment alone in patients who have had recent stroke due to vertebral stenosis.

Who can participate?
Women or men over 20 years of age who have had a recent stroke and also have vertebral stenosis.

What does the study involve?
To find out which treatment is better, half of the patients entering the study will be allocated to treatment by stenting and the other half will be treated with standard drug treatment alone. Which treatment you are allocated to will be decided by a computer. This random allocation is important if we are to determine fairly which of the two treatments is better. All patients entering the study will receive the best possible medical treatment including aspirin or similar tablets and treatment of risk factors such as high blood pressure and cholesterol. If you agree to take part your GP will be informed and you will be seen by a neurologist or stroke doctor about 1 month after your allocated treatment, and at 1 year. We will also contact you by telephone at 6 months and yearly from year 2 onward until the end of the study. At 1 year we will perform a further MRI or CT scan to determine the degree of narrowing in the artery. You will be asked to fill in a diary recording contact with Health Services. Any travel expenses incurred from the visits of this study will be reimbursed.
Stenting will be carried out by an experienced radiologist. He/she will insert a fine wire and tube

into an artery in the groin (or occasionally the arm) and this will be used to feed the stent through the blood vessels into the neck. It will be placed across the narrowing in the vertebral artery. This is usually done following a local anaesthetic injection into the groin but you will stay awake during the procedure. Balloons may also be used to dilate the artery before inserting the stent. Sometimes, if the radiologist feels this is a better treatment, the narrowing will be treated by the balloon alone (angioplasty) without insertion of a stent. X-ray pictures (angiography) will be taken immediately before, during, and after stenting to make sure that the wire and stent are in the correct place. In occasional patients the angiography may show that stenting is not possible, or that the degree of narrowing is not as bad as we thought and therefore stenting is not necessary. If this is the case you will be treated with best medical therapy alone.

What are the possible benefits and risks of participating?
All patients taking part in the study will receive careful follow-up and the opportunity to benefit from advances in treatment. Stenting carries a risk of causing a stroke at the time of treatment. Previous studies have suggested this is about five per every hundred patients. There is also a risk of about one in every hundred that angiography will cause stroke. On the other hand, if we do not treat the stenosis there is a risk of having a further stroke. We are not sure whether the risk of stenting is greater than the risk if we do not perform the stenting, and that is why we are carrying out the study. Angiography and stenting may also result in bruising at the site of the introduction of the stent (usually the groin). There can be temporary pain or discomfort in the neck when the balloon is blown up. If you receive stenting then X-rays are required to allow us to ensure that the stent is placed in the correct position and this does involve a small radiation dose which may carry a small risk of induced cancer (1 in 1300).

Where is the study run from?
This study is being co-ordinated from St George's, University of London and the University of Cambridge (UK).

When is the study starting and how long is it expected to run for?
The study started in March 2008 and will run until November 2017.

Who is funding the study?
The Stroke Association and the NIHR Health Technology Assessment Programme.

Who is the main contact?
Prof Hugh Markus

Study website
http://www.vist.org.uk/

Contact information

Type(s)
Scientific

Contact name
Prof Hugh Markus

Contact details
Department of Clinical Neurosciences
R3, Box 83

Cambridge Biomedical Campus
Cambridge
United Kingdom
CB2 0QQ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Vertebral artery Ischaemia Stenting Trial

Acronym
VIST

Study objectives
To compare the risks and benefits of vertebral angioplasty and stenting for symptomatic vertebral stenosis compared with best medical treatment.

Protocol can be found at: http://www.vist.sgul.ac.uk/vist-protocol-version-7.0-04dec2013.pdf

On 06/02/2013 the following changes were made to the record:
1. The target number of participants was updated from 1302 to 540
2. The overall trial end date was updated from 01/03/2016 to 01/11/2017

Ethics approval required
Old ethics approval format

Ethics approval(s)
Charing Cross Research Ethics Committee, 24/04/2008, ref: 08/H0711/2

Study design
Multicentre randomised controlled open prospective clinical trial comparing vertebral stenting with best medical treatment.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.vist.sgul.ac.uk/vist-patient-information-sheet-version-8-04-dec-2013-clean.doc

Health condition(s) or problem(s) studied
Stroke/vertebral stenosis

Interventions
Current interventions as of 06/02/2013:
Patients will be randomised to treatment by stenting or standard drug treatment alone. All patients entering the study will receive the best possible medical treatment including aspirin or similar tablets and treatment of risk factors such as high blood pressure and cholesterol. Patient assessments will be taken at one month after your allocated treatment, and at one year. Patient follow-up via telephone will range from 2 years for the last recruited patients to up to about 8 years for first patients recruited. At one year a further magnetic resonance imaging (MRI) or CT scan to determine the degree of narrowing in the artery.

Stenting will be carried out by an experienced radiologist. He/she will insert a fine wire and tube into an artery in the groin (or occasionally the arm) and this will be used to feed the stent through the blood vessels into the neck. It will be placed across the narrowing in the vertebral artery. This is usually done following a local anaesthetic injection into the groin but you will stay awake during the procedure. Balloons may also be used to dilate the artery before inserting the stent. Sometimes, if the radiologist feels this is a better treatment, the narrowing will be treated by the balloon alone (angioplasty) without insertion of a stent. X-ray pictures (angiography) will be taken immediately before, during, and after stenting to make sure that the wire and stent are in the correct place. In occasional patients the angiography may show that stenting is not possible, or that the degree of narrowing is not as bad as we thought and therefore stenting is not necessary. If this is the case you will be treated with best medical therapy alone.

Previous interventions until 06/02/2013:
Patients will be randomised to treatment by stenting or standard drug treatment alone. All patients entering the study will receive the best possible medical treatment including aspirin or similar tablets and treatment of risk factors such as high blood pressure and cholesterol. Patient assessments will be taken at one month after your allocated treatment, and at one year. Patient will also be contacted by telephone at six months and at two, three, four and five years post entry to the study. At one year a further magnetic resonance imaging (MRI) or CT scan to determine the degree of narrowing in the artery.

Stenting will be carried out by an experienced radiologist. He/she will insert a fine wire and tube into an artery in the groin (or occasionally the arm) and this will be used to feed the stent through the blood vessels into the neck. It will be placed across the narrowing in the vertebral artery. This is usually done following a local anaesthetic injection into the groin but you will stay awake during the procedure. Balloons may also be used to dilate the artery before inserting the stent. Sometimes, if the radiologist feels this is a better treatment, the narrowing will be treated by the balloon alone (angioplasty) without insertion of a stent. X-ray pictures (angiography) will

be taken immediately before, during, and after stenting to make sure that the wire and stent are in the correct place. In occasional patients the angiography may show that stenting is not possible, or that the degree of narrowing is not as bad as we thought and therefore stenting is not necessary. If this is the case you will be treated with best medical therapy alone.

The previous sponsor for this trial (up to 24/04/2014) was:
St George's University of London (UK)
St George's Research Office
Ground Floor Hunter Wing
Cranmer Terrace
London
SW17 0RE
United Kingdom

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 06/02/2013:
Fatal or non-fatal stroke in any arterial territory (including periprocedural stroke) during trial follow up

Previous primary outcome measures until 06/02/2013:
Fatal or disabling stroke in any arterial territory (including periprocedural stroke) defined as a Rankin score of greater than or equal to three, at three months post stroke.

Secondary outcome measures
Current secondary outcome measures as of 06/02/2013:
1. Fatal or non-fatal stroke in any arterial territory (including periprocedural stroke) at three months post-randomisation
2. Posterior circulation stroke (including periprocedural stroke) during follow-up
3. Periprocedural stroke or death (within 30 days of procedure)
4. Posterior circulation stroke and TIA during follow-up
5. Any disabling stroke (defined by a Rankin >=3) during follow-up
6. Death of any cause during follow-up
7. Restenosis in treated artery during follow-up
8. NHS and personal social services costs
9. Quality-adjusted life years
10. Within-trial and long-run incremental cost-effectiveness

Previous secondary outcome measures until 06/02/2013:
1. Posterior circulation stroke (including periprocedural stroke) during follow-up
2. Posterior circulation stroke and TIA during follow-up
3. Periprocedural stroke and death (within one month of procedure)
4. Periprocedural stroke, death, and TIA (within one month of procedure)
5. Restenosis in treated artery during follow-up

Overall study start date
01/03/2008

Completion date

01/11/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 06/02/2013:
1. Women or men aged greater than 20 years of age
2. Symptomatic vertebral stenosis resulting from presumed atheromatous disease
3. Severity of stenosis at least 50% as determined by magnetic resonance angiography (MRA) or computed tomography angiography (CTA) or intra-arterial angiography
4. Symptoms of transient ischaemic attack (TIA) or stroke within the last three months
5. Patient able to provide written informed consent, be willing to be randomised to either treatment, and be willing to participate in follow-up
6. If randomised to stenting, this can be performed within two weeks after randomization.

Previous inclusion criteria until 06/02/2013:
1. Women or men aged greater than 20 years of age
2. Symptomatic vertebral stenosis resulting from presumed atheromatous disease
3. Severity of stenosis at least 50% as determined by magnetic resonance angiography (MRA) or computed tomography angiography (CTA) or intra-arterial angiography
4. Symptoms of transient ischaemic attack (TIA) or stroke within the last six months
5. Patient able to provide written informed consent, be willing to be randomised to either treatment, and be willing to participate in follow-up

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
540 (100 in the feasibility phase as of 19/04/2011)

Total final enrolment
61

Key exclusion criteria
1. Patients unwilling or unable to give informed consent
2. Patients unwilling to accept randomisation to either treatment arm
3. Vertebral stenosis caused by acute dissection as this has a different natural history and usually spontaneously improves
4. Patients in whom vertebral stenting is felt to be technically not feasible e.g. access problems
5. Previous stenting in the randomised artery
6. Pregnant and lactating women

Date of first enrolment
01/03/2008

Date of final enrolment
01/11/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cambridge Biomedical Campus
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust & University of Cambridge (UK)

Sponsor details
c/o Stephen Kelleher
R&D Manager
Cambridge University Hospitals
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type
University/education

Website
http://www.cuh.org.uk/

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type

Charity

Funder Name
Stroke Association

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
NIHR HTA Programme

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2019	21/08/2019	Yes	No